Focus on the new conference for the Royal Pharmaceutical Society

THE ROYAL PHARMACEUTICAL SOCIETY CONFERENCE “SUPPORTING PATIENT AND PROFESSIONAL DECISION MAKING” TOOK PLACE ON 5 AND 6 SEPTEMBER 2010. THIS SUPPLEMENT CONTAINS HIGHLIGHTS / SCIENCE THE SUPPLEMENT ALSO CONTAINS A SHORT REPORT FROM THE UK-PHARMSCI2010 CONFERENCE
Something for everyone

The Royal Pharmaceutical Society conference, entitled “Supporting patient and professional decision making”, covered a wide range of topics. One of many themes that emerged is that pharmacists must actively decide to participate in clinical, commissioning and communications ventures if they wish to see the profession advance. This theme has already been touched on in The Journal’s news coverage of the conference (PJ, 11 September, p258) and is more fully explored in this supplement.

Conference chairman Marjorie Weiss, from the University of Bath, looks back over 13 years of research into decision-making about the taking of medicines. In her keynote speech she looks at the issue from many aspects: from the point of view of customers (who behave differently as patients), the roles of counter staff, pharmacists and GPs, to the increasing importance of concordance (pC4). “The quest to find out why people decide the way they do, and how decision are acted out in the context of a professional-patient interaction, has been the fundamental intellectual driving force behind my research,” she states.

The next report covers newer clinical roles for community pharmacists (such as raising awareness of lung cancer) counterbalanced by an account of the way the public views pharmacists not as clinicians but as “specialist sales technicians” (pC7).

This is followed by a report of the speech the new chief executive, Helen Gordon, made to the conference. In describing the RPS of the future (pC8) she said: “You will see an organisation that looks at every issue through the eyes of its members, dealing with what matters for members, putting their view and the case for pharmacy at every opportunity.”

Pharmacogenomics and pharmacogenetics are next. Research on this has been discussed at previous Society conferences; this year, the focus is on the implications for personalised medicines (pC10). According to David Thurston, from the University of London, personalised medicine is the future of practice, and pharmacy schools and pharmacists should seize the opportunity to become the front runners who can apply pharmacogenomic services. “If we don’t other professionals will,” he warns. This is echoed by Joy Wingfield, from the University of Nottingham, who said: “Capitalising on these new forms of technology ought to be a rewarding option to get closer interaction with patients, their relatives and other healthcare professionals.”

Winner of this year’s Practice Research Award Katherine Payne, from the University of Manchester, points out that pharmacogenetics is, in theory, the perfect solution to the challenge of maximising value for money from medicines, and targeting medicines in this way could stop scarce healthcare resources being wasted. She explains that to understand the added value of pharmacogenetic tests it is necessary to identify and quantify the true costs and benefits of introducing these into healthcare systems (pC11).

The next report exhorts pharmacists to become involved in research — something they have, historically, not been good at all. “We as a profession can only move forward where the areas we’re moving into have got a robust evidence base,” says Terry Maguire, community pharmacist from Belfast (pC12).

All is not lost, however, because the next section describes the highlights of the over 100 research abstracts that were presented at the conference. They reveal that, at least in some circles, research is alive and kicking (pC13).

The last four pages are devoted to coverage of UK-PharmSci 2010, the conference organised by the Academy of Pharmaceutical Sciences. Until 2009, this conference was integral to the British Pharmaceutical Conference but, with the separation of the Society’s functions, the aims of scientists were thought to be better served in a different forum (ppC17–C20).
Remote supervision must be looked at more broadly

The debate on remote supervision should focus on the job pharmacists perform, and not on the location where it takes place, according to John Cromarty, director of pharmacy for NHS Highland. In a fringe session on supervision, Mr Cromarty argued for a broader look at the issue of remote supervision. The debate was chaired by vice-chairman of the Royal Pharmaceutical Society’s English Pharmacy Board Sid Dajani and centred on the eight principles for supervision (PJ, 7/14 August 2010, p161).

Mr Cromarty suggested that remote supervision could be of use in areas where access to a community pharmacy is limited. He pointed out that in his health board area of 12,500 square miles, half the population obtain their medicines from dispensing GP practices and do not have access to community pharmacists. Such people are often the most vulnerable and this gap of service provision is in some places being filled by non-pharmacists, he said. For example, pharmaceutical companies are providing home care with no one to oversee the safety or efficacy of combined regimens patients are receiving, he said. He emphasised that confining the discussion to pharmacists staying in the pharmacy would affect the most vulnerable of patients.

Mr Dajani remarked that the issue is one of flexibility and suggested that different pharmacy teams could be developed to ensure pharmacists are both in the pharmacy fulfilling a patient-facing role and in the community.

Margaret Allan, from the Welsh Centre for Pharmacy Professional Education, also highlighted the issue of rurality and access, and stressed the need to “future proof” plans for remote supervision to take this into account.

Taking the more conventional view, EPB member Graham Phillips said he was not prepared for the pharmacist to be removed from an often unpredictable scene, explaining that pharmacists manage a complex work environment. He added: “You never know what the query is that is going to lead to a significant intervention.” He said that day-to-day processes cannot be unpicked to separate those that need supervision from those that do not. He also argued that the added value of pharmacists is in their ready availability, not dispensing, which could be affected by future remote supervision legislation.

Pharmacists do not think of themselves as scientists

Most pharmacists do not think of themselves as scientists and this attitude should change, according to Duncan Craig, head of pharmacy at the University of East Anglia.

In a session exploring science in pharmacy education, Professor Craig argued that pharmacy needs “hard science” to underpin practice and understanding, adding that it is science that makes pharmacists special.

He said: “A lot of medical degrees have gone down a clinical road and they are trying to back pedal because they are worried about the lack of underpinning knowledge that medical students are coming out with. We would be incredibly foolish to try to go down the same road. . . . We are the only people who understand medicines right from the word go through to administration to patients. That is our unique selling point.”

Professor Craig also expressed the need for science to be contextualised in clinical scenarios to help students understand its importance.

“A pharmacist needs an understanding of the spectrum of how you go from fundamental science, how it meets a relevant clinical problem and how that pertains to patients and the public,” he said.

Professor Craig, who is also representative for the Council of University Heads of Pharmacy Schools on the Royal Pharmaceutical Society’s Assembly, rejected the claim that students do not like science. Instead he blamed university teaching methods for not delivering the subjects in an understandable and interesting way, pointing out that the most popular academic at his school teaches synthetic chemistry.

Professor Craig praised pharmacy students, saying they are more clinically aware and have better communication skills than in the past. The degree, he said, has “never been better”.

Duncan Craig praised modern pharmacy students (Damian Prestidge)
Sharing decisions about medicines: views of patients and professionals

In this article based on her address to the conference, Marjorie Weiss, head of pharmacy practice at the University of Bath and conference chairman for 2010, looks back on her 13 years of research into decision-making about medicines and concludes that it has identified some benefits of pharmaceutical services.

Decisions pervade life. They are an intrinsic part of being human. In the NHS, common terms such “patient choice”, “drug of choice”, “Choosing health” and “Choose and book” remind us of the ubiquity of the decisions that permeate healthcare. The quest to find out why people decide the way they do, and how decisions are acted out in the context of a professional-patient interaction, has been the fundamental intellectual driving force behind my research. This research covers a broad range of subjects from why people take their medicines (or not), how people decide upon where to go for pharmacy services, how prescribers make prescribing decisions and how patients and professionals share decisions in the consultation.

Here, I will focus selectively on some of my research over the past 13 years that best exemplifies these decision-making themes and reflects my interests in pharmacy, social science and medicine.

Patients and customers

When I originally started to become involved in research, I was of the view (like many other healthcare professionals) that patients who are prescribed a medicine by a doctor should do as they are told and take it. It was only when I began research into patients’ views about their medicines that I realised three things:

• That, for some patients, whether or not to take a medicine was an active, considered decision
• That many patients were quite reluctant to take a medicine even if it were clinically necessary
• That those who choose not to take a medicine could have a good, rational reason

This, and subsequent research, coincided with the development of concordance and the importance of eliciting patients’ view on taking their medicines and involving patients in decisions about their treatment.1,2

The ability of individuals to make active, considered decisions was reinforced in other work investigating customers’ expectations and choices when visiting a pharmacy.3 For some, convenience and being able to purchase something anonymously was paramount, although for others a personal relationship with an individual pharmacist was both valued and played a key part in their ongoing healthcare. Interestingly, this variation also occurred for an individual depending on the context: a customer might select a different kind of pharmacy depending upon the nature of the service they required.

Furthermore, customers’ expectations and perceptions about pharmacies influence why they might select a pharmacy, particularly for a sensitive issue such as purchasing emergency hormonal contraception. Some women’s perceptions around the convenience, anonymity and ease of access associated with pharmacy provision, meant that some were uncomfortable with other women, particularly younger women, obtaining EHC from a pharmacy.4,5 These individuals favoured a more paternalistic, lecture-based service for younger women “enforcing responsibility on them” although they themselves hated being patronised in this way when they had received such a service in the past.4 In one sense this is good news for pharmacies in that women did not associate a paternalistic service with a pharmacy. However it also suggested that a pharmacy EHC service, because of its association with commerce, was less “professional” than other health venues providing EHC. For women seeking EHC from a pharmacy, the research suggested they saw themselves as customers, whereas those seeking EHC from a walk-in centre saw themselves as patients.5

Pharmacists, GPs and counter staff

If one side of the coin is about patients and customers making decisions about taking a medicine or choosing a pharmacy, the other side relates to professionals making decisions about either prescribing or selling a medicine.6 One of the first pieces of research I conducted concerned an investigation into why doctors prescribed in situations where there was no obvious clinical need.7,8 The clinical situation most GPs described was when they prescribed an antibiotic for what clinically appeared to be a viral infection. This research provided a fascinating description of influences and situations in which they were more likely to prescribe “irrationally”: at the end of a busy day or when they were running behind time; to get rid of an annoying or demanding patient; to maintain a relationship with a patient or when they thought they wanted to provide something tangible like a prescription; and to feel they were doing something to help a patient.9 Prescribing was used as a strategy to cope with a variety of patient, practice and workload pressures.

We concluded that although the use of a prescription in this way does not fit with conventional definitions of rational prescribing (eg, safety, efficacy, appropriateness and cost-effectiveness), it is nonetheless a rational, human response to a complex social situation.

It is recognised that most interactions in a community pharmacy are managed, either entirely or in part, by medicines counter assistants (MCAs). With an increasing focus on the clinical role of pharmacists and MCAs, we investigated customers’ views on being asked unsolicited questions about an OTC medicine purchase and, subsequently, how MCAs managed these encounters.10 This early research suggested that some customers did not like being asked questions in a community pharmacy and saw the purchase of an OTC medicine as their sole responsibility.

Subsequent research used observation and interviews with MCAs to investigate how they moved talk on in a pharmacy from a predominantly retail discourse to a clinical one.11 There were several instances where customers were reluctant to answer questions. In these encounters MCAs used a number of strategies to try to facilitate the customer answering their questions. These strategies included extending or rewording their questions, or by asking questions or providing advice while they were processing the customer’s sale thereby indicating that the sale was not threatened. During interviews, MCAs mentioned that, although some customers provided all the right answers to their questions, these answers sometimes lacked conviction and MCAs tried to take steps to engage them in more meaningful dialogue.11

With the passing of legislation to enable pharmacist and nurse prescribing in 2003,
there came the opportunity to investigate pharmacist prescribing under the then new supplementary prescribing arrangements. Although prescribing is normally conceptualised as the process of writing a prescription at the end of a consultation, it was notable in this research that some of the new pharmacist prescribers had difficulty assigning a clear meaning to what was meant by prescribing. There was confusion about the terms used in secondary care (transcribing, authorisations to supply) and whether they constituted prescribing. Some pharmacists queried whether recommending a warfarin dose to a patient (who had dispensed medicines in multiple warfarin strengths at home) after appropriate haematological monitoring was actually prescribing. Indeed, respondents suggested that supplying an OTC medicine engaged in cognitive processes so similar to prescribing that it could (or should) be considered prescribing.12–13

Another important finding was pharmacist prescribers’ emphasis on identifying and circumscribing their area(s) of clinical competence. Pharmacist prescribers were acutely aware of their clinical responsibilities as new prescribers and the need to prescribe safely. What was interesting was the way pharmacists discussed how committed they were to being a “good prescriber” and that knowing the limits of what they could prescribe was not only necessary, but a professional ideal.12

Sharing decisions
Most of my recent work has focused on the wider concordance agenda, including patient-centred consultation behaviour, sharing decisions with patients and engaging with the patient as a “whole person”, within his or her broader psycho-social context.

It is an area of research and practice development that has been growing since the 1990s, with a recent development being the National Institute for Health and Clinical Excellence guidance on adherence issued in January 2009.14 The key features of involving patients in decisions about their medicines included in this NICE guidance is shown in the Panel overleaf.

Having become interested in this topic, I was struck by how many tools were available to assess shared decision making. For example, there were rating scales, checklists for specific behaviours, a form of coding talk...
called interactional analysis, and feedback forms. There also seemed to be quite a bit of conceptual overlap between shared decision making, patient-centred behaviours and concordance. Not surprisingly, different tools measured different types of patient-centred skills such as using open questions, clarifying patient concerns, displaying empathy, conveying information, giving options or development rapport. Because I did not wish to create yet another tool, I decided to conduct a piece of research investigating two previously validated tools used to assess shared decision-making in doctor-patient consultations. This research involved recording 123 such consultations and then sending anonymised copies of them to the expert developers for each of the two tools.

Notable findings from this research included the low shared decision-making scores achieved by the doctor participants and the lack of agreement between the two tools. Although both tools looked as if they were conceptually similar, they were measuring quite different things.

Two ideas came out of this research. One was about the difficulties of measurement such that there was a real disjunction between theoretical definitions of shared decision-making and the practicalities or limits of measurement. The second thought was about the potential application of these sorts of tool to pharmacy consultations, in both a community pharmacy and with pharmacist prescribers. This second idea has since informed the design of the research I am currently conducting.

The application, and measurement of shared decision-making or patient-centred behaviours in pharmacist prescriber-patient consultations, was also informed by my earlier pharmacist supplementary prescribing work. Qualitative findings from these new prescribers suggested that some pharmacists saw themselves as providing quite a different service to patients from the traditional doctor-patient consultation. They did not see themselves as “mini-doctors”. These prescribers saw their role as providing a considered and patient-centred consultation which was focused on medicines information. This reinforced to me the potential benefits of a pharmacist-led service, which was different from, but complementary to, a doctor or nurse-led service.

The communication element of pharmacist-patient consultations has become quite an important part of my current research. The difficulties of integrating the clinical aspects of a consultation with the demands of good communication have been long recognised in the medical literature. Community pharmacy has the additional challenge of occurring in a retail environment where, as noted earlier, moving customer discussions onto a clinical plane can be difficult. Assessing the quality of consultations in community pharmacies can be challenging both in terms of measurement and identifying appropriate scope of practice.

In this context, an increasingly popular approach is to use simulated patients or “mystery shoppers” to investigate the appropriateness of OTC sales. Instead of the more punitive approach adopted by the Which? report, recent studies have used simulated patients in a formative role so that pharmacists can obtain constructive feedback on their performance and use this to improve the quality of service they provide. We conducted a simulated patient research study designed to integrate the assessment of both clinical and consultation skills used by community pharmacists. Consent pharmacist participants were also provided with constructive feedback on their consultations. We found that there were many good communicators in community pharmacy. However some aspects pharmacists did better than others. Community pharmacists engaged in good eye contact and had a non-judgemental approach, but they were less good at providing opportunities for customers to ask questions or at signposting them to further support.

**Conclusion**

In conclusion, decision-making in all these guises has provided fertile ground for research and has led me to many new insights into how patients, customers, pharmacists, MCAs and doctors make decisions. This includes how people make choices but also how decisions are influenced, negotiated and changed throughout the course of a professional-patient interaction. It has identified some of the benefits of pharmaceutical services and the direction where the future of pharmacy might lie.

**References**

Delayed diagnosis of lung cancer is a problem in the UK compared with the rest of Europe, and pharmacists can play a key role in raising awareness of early symptoms, according to Michael Peake, consultant and senior lecturer in respiratory medicine at the University of Leicester.

He presented data that demonstrate chemotherapy does not have a large impact on long-term survival; the most impact comes from early diagnosis and subsequent surgery.

Dr Peake listed possible ways to achieve early diagnosis, including screening, increased public awareness and increased primary care awareness, easier access to diagnostics, better risk assessment, electronic decision support tools and widening sources of advice, for example, by providing it through pharmacists and practice nurses.

He put diagnostic delays in lung cancer down to a general level of ignorance among the public of symptoms (see Panel) and of the potential for effective treatment, stoicism or fatalism, a reluctance to trouble busy doctors and the inconvenience of GP appointments.

He explained that most of the lung cancer messages to the public are around the link between lung cancer and smoking, and lung cancer and death. “There has not been any attempt to get across an early detection message with lung cancer at all,” he said.

Dr Peake believes the public need to know that early symptoms of lung cancer are not usually severe, and that early detection saves lives.

It is also important to highlight that non- and ex-smokers can get lung cancer but that stopping smoking at any age reduces the risk.

Promoting a low threshold for chest x-ray would also have an effect, he said.

Dr Peake believes that pharmacists have a role to play in raising awareness of the disease among their customers.

“Cough must be among the commonest persistent symptoms you come across in the pharmacy,” he observed. Widening the range and nature of health-related advice, as well as better collaboration between all sectors of the healthcare system will be key to improving early diagnosis, he believes.

However, he added that more evidence about the impact of awareness campaigns is needed and suggested that pharmacists could help with collecting these data.

### SYMPTOMS OF LUNG CANCER

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### Public see dispensing as key role

Patient-centred professionalism in community pharmacy was the focus of a presentation by two researchers from the University of Swansea. Marcus Doel and Hayley Hutchings described the findings from their recent study, funded by the Pharmacy Practice Research Trust, which aimed to clarify the concept.

They conducted a series of workshops with experienced (n=14) and newly qualified (n=10) community pharmacists, pharmacy support staff (n=4), stakeholders (n=5) and the public (n=6). Through the workshops they identified 11 key themes, which encompassed positive and challenging examples of patient-centred professionalism, and gained a consensus on how important each was.

The themes, in order of importance, were safety, professional characteristics, relationship with patients, confidentiality and privacy, accessibility, training, professional pressures, services, environment, changing professional roles and patient characteristics.

Each theme was discussed in turn and several interesting issues emerged. For example, Professor Doel explained that, although pharmacists want to carry out a professional service, underpinned by reliability, trustworthiness, accessibility and friendliness, they are hampered by intense workloads, unrealistic patient expectations, and heightened commercial and regulatory pressures.

Huge role in oral chemotherapy

Community pharmacists have a huge role to play in empowering patients as oral chemotherapy becomes more common, said Sandra Melville, pharmacist at Lorn and Islands District Hospital, who was presenting on behalf of David Thomson, chairman of the British Oncology Pharmacy Association.

Patient empowerment begins with information and education, she said. It requires individuals to take care of themselves and to make choices about their care. It also requires a degree of health literacy in order for patients to make appropriate decisions about their health. Cancer patients have additional health literacy demands because they are required to process large amounts of information and make treatment decisions quickly, said Mrs Melville.

When chemotherapy is first prescribed, pharmacists working in secondary care can add benefit to many areas of discussion, either on their own or as part of a multidisciplinary team, she explained. Examples include the risks versus the benefits of treatments, toxicities and quality of life, and access to clinical trials. As more patients start to take their chemotherapy at home, pharmacists will have a role in reinforcing or initiating patient education, symptom management and proactive follow-up, she added.
The new Royal Pharmaceutical Society intends to put forward members’ views and the case for pharmacy at every opportunity, Helen Gordon, the Society’s chief executive, told the conference. “We will advocate on the issues that we know are important to you all,” she said. Graeme Smith reports

Society will look at every issue through its members’ eyes, says chief executive

The new Royal Pharmaceutical Society is an organisation that respects the differences between its members yet which will also find ways to speak with a common voice on issues that really matter for the whole profession, Helen Gordon told participants during her first speech to the conference as the Society’s chief executive.

“You will see an organisation that looks at every issue through the eyes of its members, dealing with what matters for members, putting their views and the case for pharmacy at every opportunity,” she said.

She added: “We are acutely aware that some of our members have real concerns about the way pharmacy is changing. I know that when I speak to pharmacists there is a sense that things are beyond their control. We want to return that sense of empowerment to the profession and make constructive proposals about how that can be achieved.”

She used the platform to call on other representative bodies within pharmacy to join with the Society, work with it and create a single voice for pharmacy.

That single voice would give a clear and unambiguous response to activity in Government, a clear voice to other healthcare professions and to the public. “I want to see us taking advantage of every opportunity to work together — creating a voice that is greater than sum of its parts,” she said.

Mrs Gordon was aware that some pharmacists faced an uncertain future because of the raft of new Government initiatives in the NHS, notably the shift from primary care trusts to GP consortia, and the Society would continue to campaign to retain the essential knowledge and skills demonstrated by pharmacists in these roles.

The Society was also aware that academia faced its own challenges, including maintaining robust, evidence-based research at a time of economic austerity.

“These issues are complex and the only way forward is for us to work with our members, employers, trade unions and all other relevant organisations,” said Mrs Gordon.

She explained that the Society’s virtual networks are there to connect existing networks and create new ones so members can communicate with their peers who can, in turn, offer advice, offer solutions to common problems and shape opinion within the different sectors in which pharmacy functions.

There were now discussion forums on virtual networks and the numbers of people viewing these networks had been steadily rising. “For the first time last month there were over 10,000 viewings,” she said.

Mrs Gordon told the meeting that the move towards local practice forums — a form of local activity more representative of the needs of members — is well under way. The response had been positive. “There is a

Support

Mrs Gordon explained that the Society would support all members with their continuing professional development, helping pharmacists start with their CPD or identifying opportunities for further development.

“The Society was also offering an advice service that deals with practice and ethical issues that arise in pharmacists’ daily lives. “We have a host of resources available from the new library and a portfolio of research resources to support members in developing themselves and their practice,” she said.

Recognise

Mrs Gordon told the conference that the Society would recognise the achievements of every member by awarding them with MRPharmS postnominals. Through this, every member would be recognised as a member of a valued and respected professional body.

The Society also wanted to recognise those who are developing their practice. “We’re currently working with stakeholders throughout the profession to develop a nationally recognised framework, the intent being to provide members with a career pathway with recognition for higher level competency,” Mrs Gordon said. Pharmacists in England, Scotland and Wales that she had met had all talked to her about the value of such an approach.

This approach would fundamentally change the way the profession can flex and adapt to a changing environment, she said, and would become increasingly important as technology and public policy have an impact on the profession. “A pharmacist working in, say, Newcastle who has developed expertise in sexual health services should be able to transfer seamlessly to anywhere else in Britain without any additional hoops to jump through. More than that, this helps patients and the NHS make the most of their valuable skills,” Mrs Gordon declared.

Network

Turning to the Society’s third value, network, Mrs Gordon said that professional isolation is an issue that community pharmacists in particular face and there was much to learn about the professional networks that have grown up to meet the need of specialists in hospitals and locums.

She went on to highlight the Society’s five values that would underpin everything it does as a professional body on behalf of members, namely: support, recognise, network, lead and develop.

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PHARMACY IN THE MEDIA

Pharmacy has been evident in the media over the previous year, Mrs Gordon told the conference. The Society had been proactively running media campaigns that highlight innovation, such as hepatitis C testing in community pharmacy, and asked for things to change. “We would like to see this rolled out across the NHS, linking into our lobbying work,” she said. “And we are being ‘proactively reactive’ — when medicines shortages hit the headlines we made sure the media understood the lengths our members went to in order to reduce the impact on patients.”

In addition to this the Society, especially staff in the museum, had been instrumental in getting a pharmacist on four hours of prime time television in the form of the “Victorian pharmacist” series.

What’s next?

For the future, the Society has announced an alliance with the No Smoking Day charity. “We are also working with and through the profession investing in expert media spokespeople for specific clinical areas nationally and as well as creating a regional network so we can be responsive to any journalist’s enquiry about medicines or pharmacy,” said Mrs Gordon.
tangible feeling that members want these forums to be a place to exchange views and learn, and as a channel of communication to the staff at the Society,” she said. LPFs would be used to campaign locally, and as a vehicle for discussions with commissioners and other healthcare professions. They could also be used to deliver CPD, to hear about innovation and to link practice into research and science.

**Lead and develop**

On leadership, Mrs Gordon said that the Society continues to lead the debate in the Scottish and English Parliaments, in the Welsh Assembly and in the media. “We presented the political parties with our manifesto for pharmacy, highlighting what we want to see from whoever won this year’s election. We pushed for the extended rights on prescribing Controlled Drugs for pharmacists and we understand this is likely to happen in the near future. We continued to push for dispensing errors to be decriminalised and the latest information we have is that the Government will put a clause in their new Health Bill this autumn to do as we asked,” she said.

Government ministers had been touring the country seeking views on the NHS. “Well, we got there first,” said Mrs Gordon. “We’ve been out in the constituencies, engaging with MPs, demonstrating what pharmacy and pharmacists do, demonstrating how pharmacy makes a difference to the lives of patients.”

She said there is now greater understanding of pharmacy within Government across the three nations, and there were members of Parliament who could act as advocates within Parliament and speak on pharmacy’s behalf when decisions are being made that affect pharmacists’ working lives. “But it doesn’t end there,” said Mrs Gordon. “We will take pharmacy to them. We will demonstrate what pharmacy can do by offering a vascular check and lifestyle advice for every politician within the precincts of Parliament itself ... Through demonstration and persuasion, we will influence healthcare and public policy, and shape the environment in which we work.”

**In conclusion ...**

Concluding her presentation, Mrs Gordon explained to the conference that throughout the year the Society had tried to seek its members’ views before campaigning on specific issues. “We have given you all a voice within the civil service, parliaments, Assembly and the media. We will continue seeking your views and acting as a conduit for you. What you say will be one step away from the minister or the media,” she said.

Mrs Gordon said she was clear about the Society’s new role: “We will serve you. We will speak on behalf of every sector of the profession. We will seek your views again and again. We will support you through your career, we will help you achieve revalidation and offer you help to achieve a career path. We will engender debate on all issues current in the profession, offer practical and ethical advice on day-to-day issues and we will advocate on the issues we know are important to you all.”

Healthcare in the UK is undergoing substantial change, and those involved in providing care for patients are being increasingly asked to innovate, deliver, do more with the same or less. “I believe that the new Society will deliver a range of benefits that support and develop its members to be able to give evidence of the value of pharmacy and pharmacists.”
Application of pharmacogenomics will be driven by public demand

Dispensary shelves of the future may need to be much deeper and wider if the vision of the head of the University of London pharmaceutical and biological chemistry department of how pharmacogenomics might impact on pharmacy practice were to become reality. Lin-Nam Wang reports

Although financial constraints in the NHS could hold back personalised medicine, progress could be driven by public demand as is already happening in the US, said David Thurston, head of the department of pharmaceutical and biological chemistry at the School of Pharmacy, University of London. In future, pharmacists will use simple genomic testing of metabolising enzymes to set and adjust doses and monitor treatment efficacy — and this might require drug companies to make a wider range of dosage units available, Professor Thurston believes. At the moment, we generally have a one-size-fits-all approach to drug therapy but this can mean patients may not receive optimal doses, adverse drug reactions can occur and a drug may not work at all, resulting in wasted time and distress for patients and their families, he said. He pointed out that a device, Amplichip CYP450 Test, already exists to predict dose requirements [by detecting variations for CYP2D6 and CYP2C19 genes]. Pharmacogenomic technology can be used to guide drug therapies (the presence of single nucleotide polymorphism mutations can be used to predict whether a drug will work) and we are already on the way there with drugs like imatinib: “Everyone is striving to repeat the successes of Gleevec and it looks like Roche has, with a melanoma drug [PLX-4032],” Professor Thurston said. “Oncology is leading the field in personalised medicine compared with other therapeutic areas but there are other areas which will catch up,” he added. “Given their background and training across pharmaceutical, biological and analytical sciences . . . and their general expertise on drugs, pharmacists are ideally placed to be involved in pharmacogenomic testing,” Professor Thurston said. This is already happening in hospitals (in oncology) — but more awareness is required — and in industry (in drug development). He said that those in academia are educating pharmacy undergraduates and overseeing PhD research in this area. However, anecdotal evidence suggests that teaching of pharmacogenomics in UK schools of pharmacy is highly variable in quantity and quality.

“A future role for community pharmacists is less clear . . . but they could focus on simple diagnostic tests with counselling . . . I would like to see lots of pioneering projects in community pharmacy in future,” he said.

In terms of other technological developments, Professor Thurston also predicted more advanced use of biomarkers (which will allow questions such as “am I going to get cancer?”) and “what is the best treatment?” to be answered). “Personalised medicine is the future of practice and pharmacy schools and pharmacists should seize the opportunity to become the front running health care professionals who can apply pharmacogenomic services. If we don’t, other professions will,” he concluded.

People may be able to “live fast and die old” but what are the ethical, legal and social implications?

Although the wider use of pharmacogenetic testing is not far away because of its commercial benefits, pharmacists need to up their knowledge, said Joy Wingfield, professor of pharmacy law and ethics at the University of Nottingham. She used the availability of a genetic test to predict if a person will live to 100, as reported in the media in July 2010, as a prime example of the proliferation of genetic testing in the public domain. Professor Wingfield introduced delegates to “Elsi”: ethical, legal and social issues in diagnostic testing. She said that although genetic tests had a number of factors in common with many tests already performed in pharmacies (for which the Royal Pharmaceutical Society has published guidance), the sort of information genetic testing reveals leads to some interesting issues. For example, what information should be shared with children if it has implications for their health? She suggested that interpreting genetic information could pose difficulties: “Most people deal in certainties, and getting across the idea of risk and probabilities is difficult and will take time.” But she believes community pharmacists could use their scientific knowledge to put things into context.

Ethical issues include concerns over the quality of tests, consent and confidentiality and NHS resource and equity. Professor Wingfield questioned the use of tests that reveal conditions for which there is no cure or support, and raised concerns about how we might ensure that decisions to treat certain groups do not get confused with racism. She also raised the possibility that we find ourselves with more orphan drugs. For example, if a drug only works for a small group of people with diabetes it might not be seen as economically valuable and limit investment and research.

Legal issues include statutory regulation (eg, how tests should be controlled) and civil liability in terms of who might be liable for a misinterpretation. We have already seen actions from people who sue because they have lived longer than doctors predicted, although up to now they have been unsuccessful, she said.

Capitalising on these new forms of technology ought to be a rewarding option to get closer interaction with patients, their relatives and other healthcare professionals, Professor Wingfield said.
Pharmacogenetics: is it the perfect solution to scarce health resources?

Dawn Connelly reports on the work of Katherine Payne, this year’s conference Practice Research Award winner

Pharmacogenetics, is, in theory, the perfect solution to the challenge of maximising value for money from medicines, and targeting medicines in this way could stop scarce healthcare resources being wasted, said Katherine Payne, professor of health economics at the University of Manchester, and winner of this year’s conference Practice Research Award.

However, to understand the added value of pharmacogenetic tests it is necessary to identify and quantify the true costs and benefits of introducing these into healthcare systems, she added.

Not perfect

“The reality about pharmacogenetics is that it is not as perfect as one might hope,” she said, explaining that the tests are often limited to specific or single metabolic enzymes and specific adverse drug reactions. They are not 100 per cent sensitive or specific, providing only probabilistic information, she added. She also highlighted a paucity of data on how the tests affect the proportion of good responders and the subsequent impact on quality of life, how they affect the incidence of adverse drug reactions, their impact on healthcare costs, and patients’ and health professionals’ preferences for how such tests should be delivered.

Professor Payne went on to describe aspects of her research programme, which aims to provide information on the relative costs and benefits of introducing pharmacogenetic tests into clinical practice in order to support professional decision-making in the NHS.

Evidence

Her research covers two types of evidence: the development and introduction of pharmacogenetics technology into practice; and the formalisation of services to deliver pharmacogenetics technology.

Professor Payne described economic evaluations of two pharmacogenetic tests: CYP2D6 to inform the prescription of tamoxifen in breast cancer and CYP2C19 to inform the prescription of clopidogrel. In both cases, a lack of good data meant that she was unable to develop an economic model.

Professor Payne then went on to talk about the TARGET study, a prospective evaluation of the clinical and cost-effectiveness of thiopurine methyltransferase genotyping in the number of adverse drug reactions associated with azathioprine. When complete, TARGET will be the first prospective economic evaluation of a clinical pharmacogenetic testing service, she said.

However, she emphasised that, although evidence on clinical and cost-effectiveness is necessary, it is not sufficient alone to introduce pharmacogenetic testing into clinical practice.

“We also need to be aware of how clinicians will change their prescribing behaviour so we get the maximum patient benefits from the test. We also need to be clear that patients are sufficiently informed and engaged so that they understand what clinicians tell them about the pharmacogenetic test,” she explained.

Patient and clinician preferences

In order to investigate this, Professor Payne began to look at the appropriate configuration of services by comparing the preferences of patients and healthcare professionals for the key attributes of a service.

The results showed that, while both patients and healthcare professionals had similar preferences for predictive accuracy and turnaround time of results, patients wanted accurate and timely information about the tests and the results, whereas healthcare professionals were “not that bothered about whether information should be provided to patients or not”, Professor Payne concluded.

Professor Payne concluded by highlighting a recent House of Lords Science and Technology Committee report on genomic medicine. The report called for an extension of the remit of the National Institute for Health and Clinical Excellence to include evaluating the validity, utility and cost-effectiveness of new genomic tests for common diseases, including pharmacogenetic tests, along with ring-fenced National Institute for Health Research funding for further research in this area.

“However, I don’t think [the committee] has thought it through,” she said, explaining that in order to implement the report’s recommendations, the regulatory system needs to be redefined so that the evidence necessary to populate economic models is generated. There is a need to move from the current focus on sensitivity and specificity to looking at the predictive value of the tests and their place in care pathways, she explained.

“Important questions remain unanswered and given the potential for reduced research funding, we need to consider the value of additional research and direct our efforts into areas that will generate the maximum benefits for patients,” Professor Payne concluded.

Katherine Payne addresses the conference (Damian Prestidge)
Research should underpin pharmacy practice — so how can you get involved?

Practice research is crucial to the development of the pharmacy role — and anybody can get involved. Francesca Rivers reports

Providing evidence to demonstrate the value of pharmacy services is something pharmacists have historically not been good at. But now more than ever it is an area they must improve on, as a new commissioning structure is introduced along with a renewed emphasis on cutting financial waste in the NHS. “As a profession we can only move forward where the areas we’re moving into have got a robust evidence base,” said Terry Maguire, superintendent pharmacist at Maguire Pharmacy in Belfast.

Evidence base
All pharmacists can contribute to building such an evidence base, he stressed. “There are very many pharmacists who are doing research all the time, [but] they don’t actually realise they’re doing research,” he said; the key is finding a mechanism by which useful data can be captured, a process pharmacists have been poor at. It is also about asking the right questions, which are inevitably questions around service or health issues that spark a genuine interest.

Karebor Ngwerume, a community pharmacist at Brocklehurst Chemists in Hull, said levels of engagement with practice research can range from incorporating the findings of published research into everyday practice, through collecting data to feed into existing research projects via questionnaires and surveys, to formulating and carrying out a novel project. A good start, and something all pharmacists can get involved with, is evaluating the outcomes and effectiveness of existing services, she said. Pharmacists should also make the effort to respond to surveys. “We all get sent questionnaires out . . . especially if you’re near a local university, you may have undergraduates sending out questionnaires or asking you to take part in studies, and sometimes you think to yourself ‘I’m too busy to do that’. But often it doesn’t take much time to get involved, and by getting involved we’re increasing the evidence base for all pharmacists to work from,” she said.

Keeping up to date with the latest research findings and new services or methods of practice is also important, she added. For those who wish to embark on a research project of their own, advice and support is available from the Royal Pharmaceutical Society and the Pharmacy Practice Research Trust, she said (see Panel below). Pharmacists who choose to conduct their own research need to find a platform to get the evidence out to the profession, ideally through a peer-reviewed, evidence-based publication, in order for the findings to be used to inform practice, added Dr Maguire.

Being intimidated by the prospect of conducting research will be a major obstacle for many pharmacists. But the testimonies of both of the session’s speakers — on the wealth of support available, the different ways in which it is possible to contribute to research and the critical need for robust evidence of pharmacists’ worth — should combine powerfully to overcome that initial hurdle and show how effective the things that we do are.”

WORDS OF EXPERIENCE
Both Dr Maguire and Mrs Ngwerume shared some personal insights into the art of practice research, based on projects they have carried out in their pharmacies over the years:

• Having highly trained pharmacy technicians can help free pharmacist time to develop research interests
• Involving the whole pharmacy team in research projects can help them to understand the evidence base behind the products they are supplying, and make informed recommendations
• Critically reviewing published evidence helps pharmacists reflect on their own practice and degree of knowledge
• There are always a number of different approaches to answering any one practice question — it is important to adapt and tweak the research method as you learn what is and is not useful
• Projects can start small, as a single-pharmacy initiative, and expand to multi-pharmacy, regional and national pilots based on results

Other challenges include the need to maintain enough enthusiasm for the project to see it through to completion and the amount of time and effort it takes for results to be taken to publication stage, said Mrs Ngwerume.

Political sensitivities can also arise if other healthcare professionals consider pharmacists to be “encroaching on their patch”, added Dr Maguire, arguing that this is where determined pharmacy leadership becomes important in defending the interests of pharmacy.

Challenge
Finding the time to engage with research, however, emerges as the foremost challenge for all pharmacists. “Time is a huge resource [constraint], and you have to be really committed to your project,” said Mrs Ngwerume, advising that pharmacists seek advice from experienced organisations such as the PRRT on how to tackle the issue.

Pharmacists simply have to find the time for research, she said, adding: “It’s so important that research is out there . . . to show how effective the things that we do are.”
Pharmacy practice research reviewed

In total, 103 abstracts were submitted for presentation to the pharmacy practice research sessions of the 2010 Royal Pharmaceutical Society conference. Pamela Mason reviews a selection of them here.

Reading through the pharmacy practice research papers this year, I was struck by the focus on pharmacy services. I hope that like me you will be inspired by the growing evidence of benefit for pharmacy services represented in this work and be challenged to break down the barriers to implementation that remain.

Evidence base for pharmacy services

Minor ailment schemes

Baqr (University of Sunderland) et al found that community pharmacy minor ailment schemes could generate significant savings for the NHS. This was a prospective study in which all community pharmacies across five surveyed primary care organisations (PCOs) provided a minor ailment scheme. Over a month, 1,044 patients attended pharmacies with a minor ailment. When asked how they had heard of the service and what they would have done had it not existed, almost half of the people had become aware of the scheme from the pharmacy and almost a quarter from friends and family. Had the scheme not existed most patients said they would have either consulted their GP or bought a medicine, while a few would have attended the local walk-in clinic or the accident and emergency department at the local hospital. Using standard GP and A&E costs, the researchers estimated that the scheme had saved over £14,062 over a period of a month.

Reducing errors

In a study looking at the potential to reduce errors in medicines management in general medical practice, Cantrill (School of Pharmacy and Pharmaceutical Sciences, University of Manchester) found that a pharmacist-led intervention, involving computer-generated feedback, educational outreach and dedicated support with pharmacists working in each practice to support and facilitate change, resulted in greater reductions in proportions of patients at risk of prescribing errors compared with simple computer-generated feedback to the practice. Patients in the pharmacist intervention arm of this parallel group study involving 72 general practices were significantly less likely to have been prescribed a non-selective non-steroidal anti-inflammatory drug without a proton pump inhibitor if they had a history of peptic ulcer. Likewise, they were less likely to have been prescribed a beta-blocker if they had asthma or, in those aged 75 years or older, an angiotensin-converting enzyme inhibitor or diuretic without a measurement of urea and electrolytes in the previous 15 months.

Weight management

In this same trial, Howard (University of Reading) et al found that 66 per cent of the recommendations made by pharmacists to reduce hazardous medicines management were accepted by GPs. The time taken to assess cases, make recommendations and implement changes was about 20 minutes. This was shorter than expected, suggesting it would be practical for pharmacists working in general practices to undertake this type of intervention.

Weight management is a promising area for pharmacy (Ley Olkhia/Dreamstime.com)

Safer systems of work practice

Care home prescribing

Prescribing for patients in care homes is often challenging as two studies from Belfast show. Donnelly (School of Pharmacy, Queen’s University, Belfast) et al explored the influence of treatment culture on the prescribing of psychoactive medication for older people in nursing homes. Nursing homes have been described as resident-centred (least likely to use psychoactive medication), traditional (most likely) or ambiguous in terms of treatment culture. Preliminary analysis from this survey in six nursing homes (two from each culture), which involved interviews with staff and a medication audit, indicated that the culture within a resident-centred or ambiguous nursing home promotes the use of non-pharmacological methods for the management of agitated residents while the staff in a traditional nursing home were inclined to request psychoactive medication quite readily. Barry (Queen’s University, Belfast) et al surveyed all nursing home managers in Northern Ireland to explore their attitudes to the management of pain in residents with dementia. Respondents recognised the difficulties in assessing pain in these patients, but appeared to be uncertain about how best to manage it. Half of respondents thought it was safe to use opioid analgesics, but were uncertain about the risk of side effects while just over half believed that non-pharmacological methods were useful. Barriers to successful pain management were lack of staff knowledge, a lack of a standardised approach to pain management and difficulty in obtaining an accurate report of pain from the resident.

Medicines reconciliation

Continuing with the theme of patient safety, Dodds (East and South East England Specialist Pharmacy Services) measured the extent and type of unintended discrepancies identified through pharmacy-led medicines reconciliation (MR) in acute trusts delivering services across four strategic health authorities. Over a one-week period, 50 participating acute trusts documented 8,621 MRs from 49,099 admission drugs and identified 11,366 unintentional discrepancies (UDs) (an average of 1.32 UDs per MR). The author says these data can be used by NHS trusts not only to review, benchmark and monitor local MR provision but also to demonstrate the contribution of pharmacy services to patient safety.

Houston (Belfast City Hospital) et al conducted a study which led to an...
improvement in the way unlicensed medicines are prescribed, procured, supplied and administered within Belfast City Hospital. A risk assessment of the 139 unlicensed medical products in use within the hospital found that 48 of these drugs were of moderate or major risk while the rest were of low or minor risk. This finding enabled pharmacy recording of supply and hence administration time to be reduced. On a less positive note, an audit of hospital discharge summaries received by GP practices in Sutton & Merton conducted by Gauthier (NHS Sutton & Merton, London) found that they were not fully completed. Only one of 19 audit criteria (the patient’s name) was present on all the discharge summaries and only 15 per cent of summaries were received within the suggested 72 hour period. The author recommends that hospitals use a standard list of entry fields on discharge summaries with mandatory entries.

Access to medicines

Simvastatin

Most pharmacists in Scotland are not supplying non-prescription simvastatin according to the findings of Paudyal (School of Pharmacy and Life Sciences, Robert Gordon University, Aberdeen) et al. A questionnaire survey of all pharmacists in Scotland indicated that over 82 per cent did not supply simvastatin at all. Barriers had changed little since the medicine was first available without prescription and included lack of patient demand, concerns around retail prices, low evidence base and lack of access to patient medical records.

Pharmacist prescribing

Seven years after the introduction of pharmacist prescribing, two studies this year look at some of its impacts. Nesbat (University of Sunderland) et al surveyed 179 pharmacists who had undertaken prescribing courses between 2003 and 2009. Of the 98 who responded to the questionnaire, only 61 reported using their qualification. Reasons for not doing so included not defined prescribing role in their organisation, short-term projects with limited funding and prescribing not being a PCO priority.

According to a study by Stewart (Robert Gordon University, Aberdeen) et al, patients who had undertaken prescribing courses between 2003 and 2009. Of the 98 who responded to the questionnaire, only 61 reported using their qualification. Reasons for not doing so included not defined prescribing role in their organisation, short-term projects with limited funding and prescribing not being a PCO priority.

McIntosh (Robert Gordon University, Aberdeen) et al found that although most newly qualified pharmacists had thought about undertaking prescriber training in the future, they did not think it should be incorporated into the MPharm course.

Patient perspectives

Managing illness in young people

The patient’s perspective was investigated in several studies. Salesma (University of Nottingham) et al interviewed eight first- and second-year students to gain insight into managing asthma medicines at university. A key challenge for the students was taking primary responsibility for managing their condition after leaving home with support occasionally sought from parents and peers.

Morecroft (Liverpool John Moores University) et al considered potential barriers to young people’s self-management for diabetes. Interviews with health professionals, parents and young people found that the tendency for professionals to direct discussion towards parents may be better for children, but if this continues into adolescence, diabetes self-management will unlikely be adopted.

In another study on young people, McQuade (Queen’s University, Belfast) et al used focus groups to explore the views of 103 children aged eight to 14 years on the role of the pharmacist in extemporaneously preparing paediatric medicines. The children recognised the expertise of the pharmacist in making such formulations and believed that a medicine made for a specific individual would work better and be safer than an off-the-shelf product. They were also strongly of the opinion that pharmacists should involve young people in making decisions about the medicines they receive.

Medicines use reviews

Turning to patients’ views on medicines use reviews, Iqbal and Wood (Aston University, Birmingham) conducted a large-scale survey of 150 patients at various pharmacies. The majority were satisfied with the service they received. However, the patients who required medicines reviewed were more satisfied than those where medicines were not reviewed.

A further study by Latif (University of Nottingham) et al evaluated the reasons underlying patients’ decisions to accept or decline an MUR. Of the 34 patients interviewed, 26 accepted the offer of an MUR simply because they were asked and had the time. The other eight declined: two declined for lack of time, three gave no reason, and others had more complex reasons.

Communication and adherence

Compliance

Poor compliance with medication has been found in many studies, including two of the studies presented this year. Cabbín (Liverpool John Moores University) et al found that only 12 per cent of patients in a North West primary care trust were 90–100 per cent compliant with instructions for use of a steroid inhaler. Compliance had worsened (both underuse and overuse) by 20 per cent since the preceding year.

An Australian trial conducted by George (Centre for Medicine Use and Safety, Monash University, Melbourne, Australia) found that just over half of 395 patients taking anti- hypertensive medications were compliant. However, following a community pharmacy-based intervention compliance increased. Both diastolic and systolic blood pressure reduced in both the intervention and usual care groups, but the reduction in systolic blood pressure was significantly greater in the intervention group.

Patient information

Presentation of information is important for patients, particularly if literacy or numeracy is an obstacle. Hirsch (Aston University, Birmingham) et al found that English patients frequently had trouble understanding pharmacy leaflets translated for Punjabi, and Urdu readers, including the use of pictorial information, were received positively by speakers of these languages.

Knapp (School of Healthcare, University of Leeds) et al presented side effect risk information to patients in various formats. Regardless of the format, numeracy was associated with greater accuracy in perception of risk of particular side effects.

Roles, performance and practice

Professional practice

Professionalism is instilled into students as undergraduates. However, in a survey of hospital preregistration tutors, Christiou (NHS Pharmacy Practice Unit, University of East Anglia, Norwich) et al found that elements associated with multi-professional teamwork and interactions with patients are not well developed, even by the end of the preregistration year.

Continuing with the theme of professional practice, Freebone (Kingston University, Kingston upon Thames, Surrey) et al found that most students in all four years of the MPharm programme valued learning some of the scientific component of their course in a clinical environment because this was believed to be a good preparation for becoming a clinical pharmacy practitioner.

Work-related issues

Turning to work related issues, Jacobs (Centre for Pharmacy Workforce Studies, School of Pharmacy and Pharmaceutical Sciences, University of Manchester) et al focused on performance concerns in community pharmacy. Defining performance concerns was difficult for all employers but dispensing errors, poor customer service, bad attitude and an unprofessional manner were the most commonly cited.

Baquir and Campbell (Northumbria Healthcare NHS Foundation Trust, North Shields) evaluated the Health and Safety Executive (HSE) tool for evaluating pharmacists’ well-being at work. This tool was shown to be successful in benchmarking the well being of hospital pharmacists.
Local practice forums are a powerful vehicle for Royal Pharmaceutical Society members to feed their views back to the new, responsive professional body, according to speakers at an RPS conference session on developing local pharmacy leadership and networks.

Over the course of 2009 a total of 47 LPFs were established: 35 in England, seven in Scotland and five in Wales. These replaced the 120 regional branches that formerly provided a local professional network for Society members. Most of these LPFs now have a steering group in place and 44 have an online pharmacy network — or virtual network — up and running.

West Yorkshire LPF lead Gillian Hawksworth, who also headed the national LPF pilot, said the main aims of the new forums are to help shape and influence pharmacy services across all areas of practice, and empower members to make a real difference to patient outcomes.

More than just a branch?

LPFs will take forward all the benefits of branches but offer more services, according to David Morgan, of the North Wales LPF, one of the six forums established last year as part of the pilot programme. By working locally with a range of organisations — including education authorities such as the Centre for Pharmacy Postgraduate Education, commissioning bodies such as the Pharmaceutical Services Negotiating

Committee and academic institutions — LPFs will provide career advice, support practitioners in advancing their skills and secure work placements for preregistration trainees and pharmacy students, he said.

They will also promote pharmacy practice research and encourage pharmacists to build the evidence base for their services. “Every LPF needs a research champion. . . . We need to engage with local and regional research and science networks [and] raise the profile of research, to support commissioning and the development of pharmacy services,” Mr Morgan argued.

Virtual networks are also an important and innovative new offering, which can be used to hold virtual meetings, access information and training tools and share best practice via discussion forums and special interest groups.

As administrative lead for the North Wales Pharmacy Practice Forum, the virtual network for North Wales, Mr Morgan helped to develop and pilot the online networks and he stressed how importance it is for members to engage and encourage others to join in.

No standard LPF model

A toolkit explaining how to set up, fund and run an LPF is available on the Royal Pharmaceutical Society website, and is in the process of being updated to reflect LPF-building experiences to date.

However, Mr Morgan stressed that there is no standard LPF model. Each forum must work for the needs of the region it serves, and ensure the wealth of local knowledge held by former branch secretaries and leads is put to good use in the new structure. “Hopefully all of you are using your LPF facilitators. If not, make contact because they’re extremely valuable people,” he said. There are currently five LPF facilitators, one each in Scotland and Wales and three in England. A recruitment process is under way to fill two further, short-term posts, to provide additional support while the LPFs swing into action.

Challenges and choices

Key to the success of the new forums is the sharing of funding, resources, learning, contacts and particularly of expertise, said Dr Hawksworth. This sharing will, to a large extent, rely on members engaging with virtual forums in order to overcome the geographical challenge that the large LPF regions pose. Sharing the resources that were formerly held by the separate branches could present another challenge. Core funds previously allocated to individual branches are now being held centrally by the LPF, and it is up to each
LPF to decide whether the former branch budgets should remain ring-fenced or be divided out across the entire LPF according to local need. However, this bottom-up approach also presents an opportunity for funds to be shared out more fairly and spent more fully than they were in the past.

Another decision for each LPF to make is whether they will involve non-pharmacists, such as pharmacy students, preregistration trainees, pharmacy technicians and pharmaceutical scientists. Non-RPS members are currently unable to log into virtual networks and so cannot engage with online LPF meetings and discussions, despite having been valuable contributors to branch activity, highlighted Mr Morgan. This problem will need to be overcome either with an IT solution or by allowing non-pharmacists to join the RPS — an issue that members are to be balloted on.

A related question is whether non-RPS members should be charged to attend LPF meetings or use LPF resources, a decision Dr Hawksworth said will be for each LPF to make: “It is my intention still to encourage technicians in some capacity to attend our meetings, and that would extend to pharmacists with specific clinical expertise that we would like to engage with our LPF.”

Mr Morgan seconded this approach. “As a branch secretary I’ve always been inclusive; invited technicians to meetings and had joint meetings with doctors, dentists, nurses, representatives from industry.

“I think we will probably adopt a similar approach within the LPF. I don’t really like going down the road of asking people to pay,” he said.

Tool for realising the pharmacy vision
By 2020 pharmacists will achieve complete recognition as medicines experts and leaders in their field, according to the RPS’s new vision for pharmacy.

“We can only do that if we create an outstanding professional body by developing it locally,” said Dr Hawksworth.

Session chairman and director of professional development and support for the RPS Catherine Duggan commended LPFs as a conduit to the Royal Pharmaceutical Society and as a major lobbying route. But it is a two-way street, she said: members need to take ownership of their LPF and get involved in sharing best practice, supporting each other, gathering evidence and developing services in order to adapt to the changing healthcare environment with which we are now faced, she said.

RPS conference

BUILDING A SUCCESSFUL LPF

In order to establish effective local networks with the power to support pharmacists and influence service delivery, there are a number of recommended steps to be taken by LPF steering committees and their members, including:

• Drafting a budget, and agreeing an approach to sharing funds fairly across the LPF
• Using and promoting virtual networks
• Overcoming local IT problems
• Identifying local champions to lead and motivate members, and who take responsibility for getting things done
• Considering a mixture of professional, clinical, business and social meetings
• Holding local events within LPF regions, to overcome geographical barriers, and also arranging events between different LPFs
• Doing what works locally, based on experience gained through the Society branches
• Attending steering group meetings to share information about planned and held events

Many opportunities for pharmacists to engage with NICE

The National Institute for Health and Clinical Excellence needs interested parties, including pharmacists, to register as stakeholders. Matthew Wright, editor of Clinical Pharmacist, reports from a session on implementing evidence

There are many opportunities for pharmacists to engage more with the National Institute for Health and Clinical Excellence, according to Alaster Rutherford, the organisation’s associate director for implementation support.

In a session on implementing evidence in practice, Mr Rutherford explained that, for each clinical guideline being developed, NICE invites interested parties to register as stakeholders.

“We do not actively go out and seek stakeholders,” he told participants. “It is important that individual professional groups do register, otherwise they run the risk of missing out [on providing input].”

Mr Rutherford also revealed that not all NICE clinical guidelines that involve medicines have pharmacist representation on their guideline development group.

“Sometimes we find it very difficult to recruit pharmacists [to these groups],” he said, “so if you have an interest in a particular subject I would suggest you check the NICE website, particularly if you become aware there is going to be a clinical guideline produced. . . It is a self-nomination process, so you effectively apply for a job.”

Mr Rutherford pointed out to participants that the institute now produces the following types of guidance:

- Cancer service guidance
- Clinical guidelines
- Diagnostic technologies guidance
- Interventional procedures guidance
- Medical technologies guidance
- Public health guidance
- Technology appraisals
- Quality standards

The roles of consultees and commentators within the NICE appraisal process are subtly different, Mr Rutherford said. “Consultees, such as the manufacturer, national professional bodies and primary care trusts, have the right to submit evidence and to appeal against the decision of NICE. Commentators, who can be comparator manufacturers and relevant research groups, can comment on it but cannot appeal a decision.” He added: “All comments that are made on any piece of NICE guidance must be responded to. If you go to the website you will find a detailed response to every comment made.”

Mr Rutherford said there might be a perception among pharmacists “that you need to be highly academic” to respond to NICE consultations or “that you’ve got to comment on everything”. But, he told participants: “If you are only commenting on three paragraphs — or one paragraph — actually that might be a really important point that has not been raised.”

There are further opportunities for pharmacists to become involved with NICE and enhance their professional development through the institute’s fellows and scholars programme, said Mr Rutherford. There are currently 10 NICE fellows — one of whom is a pharmacist — and 20 NICE scholars. The deadline for applications for the 2011 programme is 30 November 2010, and details are available at www.nice.org.uk.
From rice to mice to man: progress towards personalised medicines

The RPS conference was preceded from 1 to 3 September by UK-PharmSci2010, a conference on the science of medicines, held in Nottingham and organised by the Academy of Pharmaceutical Sciences with the aim of bringing together researchers in the wide range of disciplines that constitute pharmaceutical science.

Joseph Chamberlain reports on selected highlights.

Overcoming barriers with dynamic delivery systems

The advantages of dynamic drug delivery systems were described to the conference by Stuart Jones (King’s College London), winner of the GlaxoSmithKline Emerging Scientist Plenary Lecture Award.

Most modern medicines consist of preformed passive delivery systems with various disadvantages, said Dr Jones. Fabrication of the preformed system is time consuming, stability concerns must be addressed, drug delivery is dictated by the drug’s own physical chemistry, the generation of high energy states is precluded and there is a lack of flexibility. There are four main barriers to delivery, said Dr Jones: the airway, the gastrointestinal tract, skin and nail.

Dynamic drug delivery is described as the construction of a temporal environment on the surface of a biological barrier to control the presentation of a therapeutic agent. For aerosols in particular, a dynamic formulation changes, either during or after dose actuation, but before deposition on a biological membrane to generate a temporal state.

The factors that can be used in devising a dynamic delivery system include supersaturation, ionisation, synthesis, superstructuring, ion-pair formation and crystallisation. An example of a dynamic drug delivery system is in a project to improve the delivery of salbutamol by the formation of an appropriate ion-pair.

The advantages of dynamic delivery systems are that they often deliver the drug in solution, highly stable premixes are possible, membrane penetration is actively enhanced, and temporal high energy states are possible, as is flexible tuning of the delivery profile, said Dr Jones.
Pleasures of a career in research & development

During a session on medicinal chemistry, David Lathbury (AstraZeneca) extolled the pleasures of a career in product research and development. The R&D role is to invent and develop robust, economic manufacturing processes for new chemical entities, to supply drug substances to progress development programmes, and to provide documentation to satisfy external regulatory authorities.

These differing needs can be conflicting. In the short term the active pharmaceutical ingredient is needed for the drug project and, in the early phase of development, this is on the critical path. At this time knowledge of how the processes will operate on scale-up is not well known and therefore there is a risk it will not work as planned.

The start point for process development programmes is the medicinal chemistry route, which is typically designed to be convergent and allow access to a variety of targets and is not designed with scale-up in mind. The route may or may not be suitable in the short term. Unless treated, these problems will show up in the later phases of drug development when processes are being transferred to manufacturing operations and can lead to costly delays, said Dr Lathbury.

The main difference between laboratory and plant is that things take longer at the plant scale. It is not just addition, heat-up and cool-down times that change. Work-up and isolation (filtration, crystallisation, phase separation) are just as important as making the right chemical bonds. The laboratory scale, where a litre can be mixed in seconds, is quite different to the large plant scale, where 50m^3 will need up to a minute. If the mixing and mass transfer effects are more rapid than the reaction rates of the desired chemistry they are unlikely to be a major issue.

The future is challenging, said Dr Lathbury, but better chemistry will help solve the problems.

Targeting microbial genes in the hunt for new drugs to fight infection

Simon Mackay (University of Strathclyde) explained that a strategy for discovering drugs for use against bacterial and parasitic infections was to target the gene of the invading microbe. His Strathclyde group has designed a series of minor groove inhibitors to act against human infections. The binder needs to have a complementary shape with the groove, complementary recognition of the groove sequence, and significant binding affinity for the groove.

At the heart of the strategy was to design a molecule that would recognise and bind to the sequence CTAG. The relevant molecule would have a head group, a heterocyclic body and a tail and variations of the three entities enabled certain rules to be formulated. High antibacterial activity requires a degree of lipophilicity via a branched alkyl group or amide isostere, 2:1 binding of the binder in the minor groove so alkyl groups cannot be too big or too close together, and control of the pKa of the tail group.

The group had discovered a lead compound with antibacterial activity (minimum inhibitory concentration 0.06mM) and selectivity (more than 600-fold) very much greater than any other of their other binders and the equal of any published compound.

Evaluation of new compounds for treating cystinosis

The synthesis and biological evaluation of pegylated-cysteamine compounds for the treatment of cystinosis were described to the conference by Graeme Kay (Robert Gordon University, Aberdeen).

He said that although cystinosis may be treated with cysteamine (mercaptamine), this treatment has severe side effects, including nausea, vomiting and gastric irritation.

Metabolites secreted in breath and sweat, manifested as halitosis and body odour, reduce patient compliance.

In a pro-drug approach pharmacologically inactive molecules are metabolically activated or tars to yield active compound. Release of cysteamine can be intracellular, thus avoiding gastrointestinal related side effects, and minimising odour problems.

A small library of PEG-cysteamine and PEG-cysteamine compounds was created and screened for toxicity. Further studies showed that PEG-cysteamine and cystamine compounds depleted the cystine burden of cystinotic cells.

Future work will centre on increasing the synthetic yield and developing the library of compounds.
Quality should be built into a product with a thorough understanding of the product and process by which it is developed and manufactured along with a knowledge of the risks involved in manufacturing the product and how best to mitigate those risks, said Simon Holland (GlaxoSmithKline).

The old way of working was to ensure quality through end-product testing. Processes were scaled up and three large-scale validation batches were made. The new way is to ensure quality through risk assessment during development, with processes mapped to demonstrate understanding of where batches can fail.

Dr Holland described how the guidelines issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) can be deployed during the development of a drug product. In these guidelines, the two main principles of quality risk management are that the evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient, and that the level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk.

In Dr Holland’s vision of the future, quality decisions would be based on process understanding and risk management, and process control would be focused on process parameters that affect product performance.

Process validation would be continuous and quality systems would support process changes by allowing flexibility in areas that are not critical to patient safety and efficacy. There would be the flexibility to change the process without prior approval from the regulatory body, he ended optimistically.

**Integrated feeder-mixer systems**

Fernando Muzzio (Rutgers University) described the characterisation and optimal design of integrated feeder-mixer systems used in continuous manufacturing of tablets and capsules. Gravimetric feeders, which are universally used to feed roller compactors and are increasingly used in continuous tableting, can generate powder streams with noisy flow rates. The lower the flow rate, or the more cohesive the powder, the greater the flow rate variability.

Although mixers can eliminate much of this noise and generate homogeneous powder streams, the components must be designed to ensure effective noise minimisation; otherwise, composition variability of the powder entering a tablet press can be excessive. A statistical analysis of the performance of the mixer as a function of critical process parameters is performed using multiple methods for determining the design space characteristics.

**The important role of excipients**

Liz Meehan (AstraZeneca) described the concept of excipient functionality-related characteristics, their role in assessing the impact of excipient variability on product performance in quality by design and their use in development of appropriate control strategies.

An excipient is any substance, other than the pharmacologically active drug or prodrug, that is included in the manufacturing process or is contained in a finished pharmaceutical dosage form. Excipients are increasingly being recognised for their role they play in pharmaceutical products. Pharmaceutical excipients contribute enormously to the efficacy of a product by providing specific special functionalities in formulations.

Functionality of excipients exists only in the context of a specific formulation. Lot-to-lot variability of excipients is to be expected, therefore formulations and processes need to be designed accordingly.

It is necessary to identify potential functionality-related characteristics for excipients in a formulation and to develop suitable characterisation methods to measure the properties of key excipients and assess the degree of variability of those excipent properties.

Over time a library of materials will develop, accompanied by a database of characterisation data. We can then model the impact of excipient variability on product performance, processability and stability and develop an appropriate control strategy, concluded Dr Meehan.
Techniques in the pharmaceutical analysis of drug inclusion products

A symposium on the analysis of drug inclusion products was presented by the Joint Pharmaceutical Analysis Group. Inclusion compounds may be defined as having one component with a cavity or spaces in which molecular entities of a second chemical species are located. There is no covalent bonding and cohesion is generally due to van der Waals forces.

Inclusion complexes
Reviewing the range of inclusion complexes available, Yvonne Perrie (Aston University) said that among them were cyclodextrins, liposomes and particulates. The choice of which to use depends on multiple factors, with optimisation required for each system or drug combination.

If liposomes are used, then the loading and release is influenced by the lipid choice and the cholesterol content. As cholesterol has certain drawbacks in pharmaceuticals, fatty alcohols such as tetracaneol may be suitable alternatives, said Professor Perrie.

Regulatory challenges
The regulatory challenges presented by drug inclusion products were discussed by Abigail Moran (Medicines and Healthcare products Regulatory Agency), who said that particular challenges related to micelle-containing products and liposome-containing products.

Some regulatory guidance is available, but is in continuous development, said Dr Moran.

Forces at play
To help understand the forces at play in drug inclusion products, Graham Buckton (School of Pharmacy, University of London) described the physiochemical characterisation of dispense systems, focusing on size, shape, surface area, flow and hardness. Professor Buckton emphasised the importance of using a range of analytical techniques in this work rather than trusting in a favoured few, showing examples of why this was important.

Improving solubility
Since most new drugs are water-insoluble, said Johan Martens (University of Leuven, Belgium), his aim was to achieve high plasma concentrations by increasing the percentage of drug dissolved in intestinal fluids. The strategy was to construct ordered mesoporous silica as a carrier for a model drug, itraconazole, thus facilitating a supersaturated solution leading to enhanced trans epithelial flux and increased bioavailability.

Tackling low solubility
Chris Frampton (Pharmorphix) described the problem of having a potent subnanomolar inhibitor with solubility in aqueous media “slightly less than that of a common housebrick”. Property modification may be through exploitation of the crystal lattice. Certain active materials appear more amenable to the formation of co-crystal phases. An accessible structural motif for hydrogen or other secondary bonding is usually necessary.

Two examples were described where successful application of co-crystal products were prepared: the neutral, non-ionisable gabapentin lactam and the weakly basic pyrimethanil where salt formation can occur.

Drug-resin complexes
David Elder (GlaçoSmithKline) described the characterisation of drug-resin complexes. These can be placed in the buccal cavity, where both favourable pH and ionic concentration ensure stability. When the complex reaches the target site, such as the stomach, ions in the body fluids at that site can exchange with the drug bound to the resin. The drug is typically absorbed before it can re-complex with the resin, hence the body acts as sink prompting further exchange.

The choice of resin and drug-resin ratio affects both in vitro and in vivo release and the choice of the preservative system. The resin particle size affects palatability, mouth feel and in vitro release. Not surprisingly, pH affects both in vitro and in vivo release but it is not relevant from a bioequivalence perspective.

Ways to transport drugs across cellular barriers and employing the BCS for formulation development

In a session on pharmaceutical technology and biopharmaceutics, Antony D’Emmanuel (University of Central Lancashire) proposed that cellular barriers, including the blood-brain barrier, could be crossed using dendrimer nanocarriers.

The phases of this work were to evaluate the permeation of surface engineered dendrimer conjugates across epithelial cells, to investigate the transport mechanisms of dendrimer conjugates across epithelial cells, to evaluate the potential of dendrimer-drug conjugates to enhance the bioavailability of drugs that are poorly soluble but are substrates of efflux transporters, selection of drug-dendrimer linker, and internalisation of dendrimers.

It was found that conjugation to dendrimers significantly enhances the solubility and permeation of poorly soluble drugs. Drug-dendrimer conjugates bypass P-glycoprotein efflux transporters in model systems for the gastrointestinal tract and the blood-brain barrier.

Classifying drug “developability”
In an industry currently focusing on efficiency, there is a desire to simplify early development. The development of drugs with poor solubility and poor oral absorption is a particular challenge to this way of thinking in early development. We need to know whether the drug and formulation properties are adequate to provide good exposure with low variability for early human studies.

James Butler (GlaçoSmithKline) proposed an interesting version of the Biopharmaceutics Classification System (BCS) for application to formulation development. The BCS enables biowaivers for new formulations of low-risk drugs. The key criteria for the US Food and Drug Administration are solubility adequate to dissolve the highest dose strength over the physiological pH range, good permeability, and rapid dissolution profiles. It is a tool to enable regulators to assess the risk of bioequivalence between test and reference formulation and offers a shorter route to approval than human bioequivalence studies.

The proposed DCS is a “developability” tool, with the realistic aim of identifying the most likely factors determining control of the extent of oral absorption (permeability, solubility, dissolution rate). The use of a simple classification system to assess the “developability” of oral drugs is attractive as key factors influencing drug absorption can be simply represented by a few key parameters and visualised by plotting position on a BCS-like two-dimensional graph. The DCS may also be useful in highlighting the potential for biowaiver extensions for some BCS class II compounds, concluded Dr Butler.